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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,444	03/20/2001	Brent Iverson	MXGN:005USC2	3269

7590 10/14/2009  
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EXAMINER
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DO, PENSEE T

ART UNIT	PAPER NUMBER
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1641

MAIL DATE	DELIVERY MODE
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10/14/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/813,444	IVERSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,6-12,15 and 18-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6-12,15 and 18-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/25/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Priority***

This application 09813444, PG Pub. No. 20040072740 filed 03/20/2001 is a continuation of 08847063, filed 05/01/1997 ,now abandoned. Application 08847063 is a continuation in part of 08447402, filed 05/23/1995 ,now U.S. Patent #5866344. Application 08447402 is a continuation in part of 08258543, filed 06/10/1994 ,now abandoned. Application 08258543 is a division of 07794731, filed 11/15/1991 ,now U.S. Patent #5348867.

### **Child Data**

Application 11317680, filed on 12/22/2005 is a continuation of 09813444 , filed on 03/20/2001.

### ***Information Disclosure Statement***

The IDS paper submitted on April 25, 2008 has been acknowledged and entered.

### ***Amendment Entry & Claims Status***

The amendment filed on May 8, 2008 has been acknowledged and entered.

Claims 1, 6-12, 15, 18-26 are pending and being examined.

Claims 2-5, 13-14, 16-17, 27-46 are cancelled.

### ***Withdrawn Rejection(s)***

Rejections under 102 and 103 in the previous office action are withdrawn herein.

### ***New Grounds of Rejection***

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6, 9, 11, 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Sharon (US 5,789,208 filed February 19, 1997).

Sharon teaches a method of obtaining a library of vectors that encode a plurality of distinct candidate of polyclonal antibodies or antibody fragments (see col. 13, lines 34-40), wherein said vector provides for cell surface expression of said candidate polyclonal antibodies (see col. 14, lines 33-37); expressing each of the antibodies or fragments thereof on the surface of a plurality of yeast host cells and selecting a yeast host cell (col. 13, lines 34-46) that expresses a desired polyclonal antibody or fragment thereof (see col. 14, lines 33-37).

For claims 6 and 9, Sharon teaches adding a sample of neoplastic tissue or antigen is then introduced to a cell population capable of producing antibodies. (see col. 10, lines 63-67).

For claims 11 and 12, Sharon teaches the vector library is obtained by administering to an animal an effective amount of selected antigen; the  $V_H$  and  $V_L$  mRNA of the animal are reverse transcribed into  $V_H$  and  $V_L$  cDNA sequences which are PCR amplified with the resulting amplified sequences linked. The linked sequences

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are PCR amplified to create a population of DNA fragments which encode  $V_H$  and  $V_L$  antibody fragments that are cloned into expression vectors and the population of cloned expression vectors expanded. The expression vectors which encode antigen- or tissue-specific antibodies or fragments thereof may be selected and the subpopulation selected expanded to produce a library. (see col. 16, line 56-col. 17, line 20).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 8, 18, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharon in view of Yokoyama (US 5,646,011).

Sharon fails to teach labeling the antigen with a fluorescent label.

Yokoyama teaches a method of identifying tumor cells by contacting a sample of tumor cells with a molecule which binds to the protein isolated. Such molecule is labeled with a fluorescent marker, radioactive isotope or enzyme. (see col. 3, lines 50-60). The protein is isolated by incorporated the nucleic acids into a recombinant expression vector which ensures good expression of the nucleic acids in a host cell. (see col. 10, lines 50-55). The host cells are prokaryotic or eukaryotic cells such as insect cells, yeast, or mammalian cells. (see col. 11, lines 10-15).

It would have been obvious to one of ordinary skills in the art to label the antigen instead of the antibody as in Sharon according to the method of Yokoyama since it is well known that the label can be either on the target or the binding partner of the target.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sharon in view of Slamon (US 4,918,162).

Sharon has been discussed above.

However, Sharon fails to teach cleaving the antibody from the cell membrane.

Slamon teaches selected host cells that express a desired antibody are subjected to cleavage to release the selected antibody or antibody fragment from the surface of the outer membrane. (see col. 7, lines 27-50).

Since Sharon teaches that the antibodies expressed in host cell of their inventions are membrane-bound type and Slamon teaches releasing the selected antibody from the surface of the outer membrane, it would have been obvious to one of ordinary skills in the art to cleave the antibodies Sharon for further analysis of the membrane antibodies or for therapeutic purposes.

Claims 10, 20-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharon in view of Civin (US 5,081,030 submitted by Applicants on IDS 3/10/05).

Sharon has been discussed above.

However, Sharon fails to teach cell separation techniques such as fluorescently-activated cell sorting/flow cytometry or magnetic separation; and subjecting cells to multiple rounds of sorting by flow cytometry.

Civin teaches well known cell sorting techniques such as fluorescently-activated cell sorting/flow cytometry or magnetic separation for cell surface ligands. (See col. 4, line 14-54).

It would have been for one skills in the art to use cell sorting techniques described by Civin to sort cells that comprises surface antibodies produced by the method of Sharon since these techniques are well known and cell sorting is necessary to obtain the host cells that contain the antibodies produced by the method of Sharon. Regarding the multiple rounds of flow cytometry, it would have been obvious to one of ordinary skills in the art to subject the host cells to multiple rounds of cell sorting using flow cytometry to obtain a highly purified cell population that contain the target antibodies.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 6-12, 15, 18-26 have been considered but are moot in view of the new ground(s) of rejection.

Since claims 9 and 10 are now being rejected for the first time, this action is made non-final.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pensee T. Do/  
Examiner, Art Unit 1641

/Mark L. Shibuya/  
Supervisory Patent Examiner, Art Unit 1641